

Message

From: Wozniak, Chris [wozniak.chris@epa.gov]
Sent: 7/31/2016 10:29:45 PM
To: Dass, Brinda [Brinda.Dass@fda.hhs.gov]; Kough, John [Kough.John@epa.gov]; McAllister, Janet C (CDC) [jvm6@cdc.gov]; Mutebi, John-Paul (CDC) [grv0@cdc.gov]
CC: Epstein, Laura [Laura.Epstein@fda.hhs.gov]; Evdokimov, Evgenij A [Evgenij.Evdokimov@fda.hhs.gov]
Subject: RE: OCC edits Working copy EA 073016.docx
Attachments: OCC edits Working copy EA 073016-CAW.docx

All,

I agree with the edits made but had two suggested alterations which you can decide to use or not as you deem appropriate. On page 74, "There is the potential for a significant environmental impact if a GE animal spreads and establishes in the environment in which it is released" could be read to suggest that the GE aspect of an introduced animal which establishes is more potentially problematic than a non-GE animal. Can we drop the 'GE' aspect?

On page 89, ".....use of OX513A mosquitoes would not adversely affect the Stock Island Tree Snail because the Stock Island Tree Snail's habitat (hammock and beach berm) does not overlap with the domestic or peri-domestic environment of *Ae. aegypti* and, therefore, the species are not expected to interact in any manner different from wild type *Ae. aegypti* present in the environment" I added in the underlined portion to again suggest that any interaction with the snail would be the same with OX513A as with wild type *Ae. aegypti* already present.

Looks good! Thanks for pulling all these comments together.

Chris

Chris A Wozniak, Ph.D.
Biotechnology Special Assistant
U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
(703) 308-4043 - office
(703) 308-7026 - fax
wozniak.chris@epa.gov

From: Dass, Brinda [mailto:Brinda.Dass@fda.hhs.gov]
Sent: Saturday, July 30, 2016 9:44 AM
To: Wozniak, Chris <wozniak.chris@epa.gov>; Kough, John <Kough.John@epa.gov>; McAllister, Janet C (CDC) <jvm6@cdc.gov>; Mutebi, John-Paul (CDC) <grv0@cdc.gov>
Cc: Epstein, Laura <Laura.Epstein@fda.hhs.gov>; Evdokimov, Evgenij A <Evgenij.Evdokimov@fda.hhs.gov>
Subject: OCC edits Working copy EA 073016.docx

Hi Chris, John, Janet, and John Paul:

Please find attached our close to final version of the Oxitec EA where we have made a few edits in response to both your comments as well as those from our Chief Counsel's office. We have left your comment bubbles in the document and provided our responses to each of them for you to see where we have edited in response to your suggestions. Please let us know if you find our responses and edits suitable or if you have further comments/suggestions for us. There are still a

few comments pending that we are working on with FDA OCC and hope to resolve by Monday or Tuesday of next week at which point we hope to move to making the document 508 compliant and ready to post. Once you have looked at the document and let us know you are ok with it we will remove your comment bubbles as well to finalize the document. If at all possible given your busy schedules it would be great to hear back from all of you by Tuesday of next week.

Many thanks

Best

Brinda